Complete Summary

GUIDELINE TITLE

Guidelines for osteoporosis in inflammatory bowel disease and coeliac disease.

BIBLIOGRAPHIC SOURCE(S)

Lewis NR, Scott BB. Guidelines for osteoporosis in inflammatory bowel disease and coeliac disease. London (UK): British Society of Gastroenterology; 2007 Jun. 18 p. [172 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Osteoporosis in inflammatory bowel disease
- Osteoporosis in celiac disease

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To review the risks of osteoporosis and fracture in individuals with inflammatory bowel disease and celiac disease with a view to identifying subgroups of patients that would benefit from screening and interventions to prevent fractures

TARGET POPULATION

Individuals with inflammatory bowel disease and celiac disease

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Screening

1. Dual energy x-ray absorptiometry (DEXA) to measure bone mineral density (BMD)
2. Quantitative ultrasound
3. Evaluation of non-modifiable risks (age, history of osteoporotic fracture, family history of hip fracture, poor visual acuity, neuromuscular disorder)
4. Evaluation of modifiable risks (body weight, use of corticosteroids, cigarette smoking, alcohol excess)
5. Screening for risk factors specific to inflammatory bowel disease (age and age at time of diagnosis; gender; measurements of weight, height, and body mass index [BMI]; duration of disease; disease site, activity, severity, and previous surgery; corticosteroid use; reduced physical activity; smoking)
6. Screening for risk factors specific to celiac disease (years exposed to gluten, gender, BMI, degree of villous atrophy, symptomatic disease, adherence to a gluten-free diet)
7. Measurement of serum alkaline phosphatase and calcium levels

Prevention

1. Education on importance of lifestyle changes (avoiding alcohol excess, smoking cessation, participation in weight-bearing exercise)
2. Management of inflammatory bowel disease (IBD) and celiac disease (proper nutrition, adequate intake of calcium and vitamin D, avoidance of steroids [IBD], strict gluten-free diet [celiac disease])

Treatment

1. Bisphosphonates
2. Teriparatide
3. Raloxifene
4. Calcitonin
5. Calcium and vitamin D
6. Strontium ranelate
7. Sex hormone replacement therapy
8. Fluoride (specifically not recommended)

MAJOR OUTCOMES CONSIDERED

- Osteoporotic fractures
- Fracture risk in specific disease (e.g., Crohn's disease, ulcerative colitis)
- Duration of disease
- Percentage of patients with osteoporosis or osteopenia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The previous guidelines, prepared in 1999 comprehensively reviewed the literature up to that time. The authors have kept details of relevant publications since then. In addition, a literature search was conducted using PubMed, Medline and Ovid databases in 2006 to identify relevant articles in English. The search terms used were: osteoporosis, osteopenia, fracture, coeliac disease, ulcerative colitis, and Crohn's disease. The reference lists of selected articles were also used to identify other relevant articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Oxford Centre for Evidence-based Medicine: Levels of Evidence

Level	Therapy/Prevention/Aetiology/Harm	Prognosis	Diagnosis	Differentia Diagnosis/Sym Prevalence St
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR+ validated in different populations	SR (with homogeneity*) of level 1 diagnostic studies; CDR+ with 1b studies from different clinical centres	SR (with homogeneity*) c prospective coho studies
1b	Individual RCT (with narrow confidence interval)	Individual inception cohort study with ≥80% follow-up; CDR+ or validated in a single population	Validating cohort study with good# reference standards; or CDR+ tested within 1 clinical centre	Prospective coho study with good follow-up##
1c	All or none±	All or none case-series	Absolute SpPins and SnNouts±±	All or none case-
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of level >2 diagnostic studies	SR (with homogeneity*) c and better studie
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study of follow-up of untreated controls in an RCT; Derivation of CDR+ or validated on split-sample only	Exploratory cohort study with good# reference standards; CDR+ after derivation; or validated only on split-sample or databases	Retrospective co study, or poor fo up

Level	Therapy/Prevention/Aetiology/Harm	Prognosis	Diagnosis	Differentia Diagnosis/Sym Prevalence St
2c	"Outcomes" research; ecological studies	"Outcomes" research		Ecological studie
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) c and better studie
3b	Individual case-control study		Non-consecutive study, or without consistently applied reference standards	Non-consecutive study, or very lir population
4	Case-series (and poor quality cohort and case-control studies**)	Case-series (and poor quality prognostic cohort studies++)	Case-control study, poor or non-independent reference standards	Case-series or superseded refer standards
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion w explicit critical appraisal, or bas physiology, benc research or "first principles"

SR, systematic review; RCT, randomized controlled trial.

*Homogeneity means a systematic review that is free of worrisome variations (heterogeneity) in the results between individual studies.

+Clinical decision rules are algorithms or scoring systems that lead to a diagnostic category or prognostic estimation.

±All patients died before the therapy became available, but some survive now on it, or some died before therapy became available, but none now die on it.

¶Validating studies test the quality of a diagnostic test, based on prior evidence. An exploratory study collects information and (for example, using a regression analysis) identifies which factors are significant.

#Good, better, bad and worse refer to the comparisons between treatments in terms of their clinical benefits and risks.

**Poor quality cohort study is one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and non-exposed individuals and/or failed to identify and control for confounders and/or failed to complete long follow-up. Poor quality case-control study is one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify and control for confounders.

++Poor quality prognostic cohort study is one with biased sampling in favour of patients who already had the target outcome, or outcomes were measured in <80%, or outcomes were determined in an unblended non-objective way, or there was no correction for the confounders.

±± An "absolute SpPin" is a diagnostic finding whose specificity is so high that a positive result confirms the diagnosis. "Absolute SnNout" is a diagnostic finding whose sensitivity is so high that negative results rule out the diagnosis.

¶¶Split sample validation is achieved by collecting all the information in a single tranche and then dividing this into "derivation" and "validation" samples.

##Good follow-up is >80%, with adequate time for alternative diagnoses to emerge (for example 1-8 months acute, 1 - 5 years chronic).

***Better-value treatments are clearly as good but cheaper or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and the equally or more expensive.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations are graded A-D based on the levels of evidence on which they are made according to the scheme devised by the Oxford Centre for

Evidence-Based Medicine. Since there is minimal evidence for or against the use of any treatment in inflammatory bowel disease and none in coeliac disease for the prevention of fracture, it has been necessary to extrapolate from the results of treatments in non G-I patients and from the effects of treatment on bone mineral density.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation

A. Consistent level 1 studies
B. Consistent level 2 or 3 studies **or** extrapolations from level 1 studies
C. Level 4 studies **or** extrapolations from level 2 or 3 studies
D. Level 5 evidence **or** troublingly inconsistent or inconclusive studies of any level

"Extrapolations" are where data is used in a situation that has potentially clinically important differences than the original study situation.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Summary of Recommendations for Preventing Fracture in Adults with Inflammatory Bowel Disease (IBD)

General Advice

- Encourage frequent weight bearing exercise (including walking, using stairs, gardening and housework) **(B)**
- Ensure nutritious diet **(C)**
- Ensure adequate dietary calcium; add calcium tablets (e.g., Adcal chewable tablet and Sandocal-400 effervescent tablet which provide 600 mg and 400 mg calcium respectively) if necessary to ensure daily intake of 1000 mg (1200 mg for postmenopausal women and men >55) **(B)**
- Seek (check calcium, alkaline phosphatase [ALP] and then consider parathormone [PTH]) and treat vitamin D deficiency **(B)**

- No smoking **(B)**
- Avoid alcohol excess **(C)**

Treat IBD Energetically to Achieve/Maintain Remission (C for bone mineral density [BMD])

Steroid avoidance:

- Early use of azathioprine/mercaptopurine
- Use steroids sparingly; consider budesonide instead of prednisolone for small bowel and caecal Crohn's
- Consider elemental or polymeric diet before steroids in Crohn's disease
- Consider biologic therapy or surgery if steroid-free remission not achieved

For those on steroids:

- All >65: consider bisphosphonate at commencement of steroids **(A)**
- <65 at high risk and requiring steroids >3 months: dual energy x-ray absorptiometry (DEXA) and consider bisphosphonate if T-score<-1.5 **(D)**
- Give vitamin D and calcium (e.g., Adcal D3 or Calcichew D3 Forte I twice daily [bd]) whilst on steroids **(D)**

DEXA for those at higher risk of osteoporosis (e.g.,[1] 2 or more of [but also refer to Boxes 1 & 2 of the original guideline document]):

- Continuing active disease
- Weight loss >10%
- Body mass index (BMI) <20
- Age >70

Treatment of osteoporosis if low-T score[2] on DEXA and risk factors, or if prior fragility fracture:

- Oral bisphosphonate long term[3] (e.g., weekly risedronate or alendronic acid) **(B)**
- Intolerance of oral bisphosphonate: consider 3-monthly iv ibandronic acid or an alternative class of drug
- Intolerance or failure of bisphosphonate in postmenopausal women or men aged >55 consider:
- Raloxifene (for postmenopausal women long term) **(B)**
- Teriparatide (by daily injection for 18 months) **(B)**
- Calcitonin by intranasal spray **(B)**
- Men with low BMD: check blood testosterone and replace if low **(C)**

[1] This is a suggestion in the absence of firm evidence

[2] There is no single T-score threshold below which treatment must be given. If risk factors are substantial, T-score of <-1.5 might be appropriate; if risk factors are slight, T-score of <-3.0 might be appropriate. Age particularly should be taken into account.

[3]But see text in the original guideline document for duration of treatment, especially in younger patients.

Summary of Recommendations for Preventing Fracture in Adults with Coeliac Disease

General Advice

- Encourage frequent weight bearing exercise (including walking, using stairs, gardening and housework) **(B)**
- Ensure nutritious diet **(C)**
- Ensure adequate dietary calcium; add calcium tablets (e.g., Adcal chewable tablet or Sandocal-400 effervescent tablet which provide 600 mg and 400 mg calcium respectively) if necessary to ensure daily intake of 1000 mg (1200 mg for postmenopausal women and men >55) **(B)**
- Seek (check calcium, ALP and then consider PTH and treat vitamin D deficiency **(B)**
- No smoking **(B)**
- Avoid alcohol excess **(C)**

Strict Gluten-free Diet (B for BMD)

DEXA for those at higher risk of osteoporosis (e.g.,[1]2 or more of [but also refer to Boxes 1 & 2 of original guideline document])

- Persisting symptoms on gluten-free diet for 1 year or poor adherence to gluten-free diet
- Weight loss >10%
- BMI <20
- Age >70

Treatment of osteoporosis if low T-score[2] on DEXA and risk factors, or if prior fragility fracture:

- Oral bisphosphonate long term[3] (e.g., weekly risedronate or alendronic acid) **(B)**
- Intolerance of oral bisphosphonate: consider 3-monthly intravenous (iv) ibandronic acid or an alternative class of drug
- Intolerance or failure of bisphosphonate in postmenopausal women or men aged >55 consider:
    - Raloxifene (for postmenopausal women long term) **(B)**
    - Teriparatide (by daily injection for 18 months) **(B)**
    - Calcitonin by intranasal spray **(B)**
- Men with low BMD: consider hypogonadism–check blood testosterone and replace if low (N.B. a normal level does not exclude hypogonadism because there appears to be androgen resistance, especially before treatment with a gluten-free diet) **(C)**

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Definitions:

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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention and management of osteoporosis in inflammatory bowel disease and celiac disease

POTENTIAL HARMS

Bisphosphonates

- Oral preparations may not be tolerated – often because of esophagitis, and they are not well absorbed.
- There is concern about osteonecrosis of the jaw although this has mainly been reported with high dose intravenous bisphosphonates for malignancy. To reduce the risk of osteonecrosis the importance of good dental hygiene should be emphasised. There is also concern about possible fractures following the accumulation of fatigue-induced damage predisposed by prolonged suppression of bone turnover.

Raloxifene

Increased risk of venous thromboembolism

Strontium Ranelate

Use is associated with a small increase in the likelihood of thromboembolism

CONTRAINDICATIONS

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Bisphosphonates should be avoided in women who could become pregnant because they can cross the placenta.

QUALIFYING STATEMENTS

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These guidelines have been prepared by the British Society of Gastroenterology. They represent a consensus of best practice based on the available evidence at the time of preparation. They may not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Lewis NR, Scott BB. Guidelines for osteoporosis in inflammatory bowel disease and coeliac disease. London (UK): British Society of Gastroenterology; 2007 Jun. 18 p. [172 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Jun

GUIDELINE DEVELOPER(S)

British Society of Gastroenterology - Medical Specialty Society

SOURCE(S) OF FUNDING

British Society of Gastroenterology

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Nina R Lewis, Specialist Registrar in General Medicine and Gastroenterology, Mid-Trent rotation, Queen's Medical Centre; Brian B Scott, Honorary Consultant Physician, Lincoln County Hospital

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the British Society of Gastroenterology Web site.

Print copies: Available from Chris Romaya, British Society of Gastroenterology, 3 St Andrews Place, Regent's Park, London NW1 4LB

AVAILABILITY OF COMPANION DOCUMENTS

Information leaflets and brochures for gastroenterologists and primary care clinicians regarding inflammatory bowel disease are available from the British Society of Gastroenterology Web site.

Additionally, targets for audit are available in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 17, 2009. The information was verified by the guideline developer on July 21, 2009.

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